Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of 24 weeks advanced weight-bearing exercises with/without quadriceps and soleus functional electrical stimulation on femoral and tibial bone density indexes and functional activities in paraplegic spinal cord injury

Protocol summary

Summary

(1)Objectives: Bone unloading due to muscle paralysis and immobility is one of the most important factors in the decline of bone mass in patients with spinal cord injury. Bones of the lower extremities in patients not receiving compressive forces caused by the weight bearing and not tensile forces caused by the contraction of muscle; So this mechanical loading by weight bearing exercises and functional electrical stimulation may be limited or improve reduce of bone density. (2)Design: Randomize control trial (3)Setting and conduct: 30 volunteers divided into 3 groups (exercise, exercise with electrical stimulation and control). Exercise group and exercise with electrical stimulation group undergo interventions for 24 weeks. Quantitative compute tomography will be taken from the distal femur and proximal tibia in both legs for all patients before and after the 24 weeks. (4)Participants including major eligibility criteria: Patients with chronic paraplegic spinal cord injury (between T2 up T12, grade A or B) (5)Intervention: Advanced weight-bearing exercises including trunk twisting and raising, quadruped, tall-kneeling with Weight shifting to different directions, alternative isometric and rhythmic stabilization contractions, and forward reaching along with functional electrical stimulation of quadriceps and soleus muscles. (6)main outcome measures (variables): Total bone mineral density, trabecular bone mineral density, cortical bone mineral density, cortical thickness, cortical cross section area and total cross section area will be measured. Also in order to assess the level of independence in daily activities and the patient's general health survey, the Persian version of the Barthel index and the SF-36 questionnaire is used. Functional and stability performance be evaluated with the number of practice of trunk twisting and raising exercise, and time exposure of quadruped, forward reaching and tall-knelling positions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304084952N3**
Registration date: **2016-11-22, 1395/09/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-11-22, 1395/09/02

Registrant information

Name
Giti Torkaman
Name of organization / entity
Tarbiat Modares University
Country
Iran (Islamic Republic of)
Phone
+98 21 8288 4509
Email address
torkamg@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of 24 weeks advanced weight-bearing exercises with/without quadriceps and soleus functional electrical stimulation on femoral and tibial bone density indexes and functional activities in paraplegic spinal cord injury

Public title
Treatment of osteoporosis in patients with spinal cord injury
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion major criteria: Traumatic paraplegic spinal cord injury (T6 up T12 ,grade A or B); Since the lesion is at least 1 year; Age between 20 and 40 years; Ability to respond to electrical stimulation of the quadriceps and soleus muscles; Normal rang of motion in the hip, knee and ankle joints; medically stable; No previous fracture in areas that are scanned; No history of metabolic diseases and other disorders affecting calcium metabolism and density of bone, early menopause, cancer, arthritis, diabetes; No use the certain drugs affecting bone metabolism including steroids, estrogens, bisphosphonates and calcitonin, fluorides, thyroid hormones, lithium, anticonvulsants and anti-androgen; No routine and regular physiotherapy including weight bearing exercise program and electrotherapy during past 6 months. Exclusion major criteria: Lack of patient's cooperation; Creation of some problems such as fractures, infections.
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Tarbiat modares university
Street address
Jalal Al Ahmad Street
City
Tehran
Postal code
14115-111
Approval date
2016-09-22, 1395/07/01
Ethics committee reference number
IR.TMU.REC.1395.364

Health conditions studied

1

Description of health condition studied
Thoracic spinal cord injury
ICD-10 code
S24.1
ICD-10 code description
Other and unspecified injuries of thoracic spinal cord

2

Description of health condition studied
Lumbar spinal cord injury
ICD-10 code
S34.1
ICD-10 code description
Other injury of lumbar spinal cord

3

Description of health condition studied
Osteoporosis
ICD-10 code
M81
ICD-10 code description
Osteoporosis without pathological fracture

Primary outcomes

1

Description
Total bone mineral density
Timepoint
Before and after 24 weeks intervention
Method of measurement
quantitative compute tomography

2

Description
Total cross section area

Timepoint
Before and after 24 weeks intervention
Method of measurement
quantitative compute tomography

3

Description
Trabecular bone mineral density
Timepoint
Before and after 24 weeks intervention
Method of measurement
quantitative compute tomography

4

Description
Cortical cross section area
Timepoint
Before and after 24 weeks intervention
Method of measurement
quantitative compute tomography

5

Description
Cortical bone mineral density
Timepoint
Before and after 24 weeks intervention
Method of measurement
quantitative compute tomography

6

Description
Cortical thickness
Timepoint
Before and after 24 weeks intervention
Method of measurement
quantitative compute tomography

7

Description
Number of practice of trunk twisting and raising exercise
Timepoint
Before and after 24 weeks intervention
Method of measurement
Count

8

Description
Time exposure of quadruped position
Timepoint
Before and after 24 weeks intervention
Method of measurement
Digital timer

9

Description
Time exposure of tall-knelling position
Timepoint
Before and after 24 weeks intervention
Method of measurement
Digital timer

10

Description
Time exposure of forward reaching position
Timepoint
Before and after 24 weeks intervention
Method of measurement
Digital timer

Secondary outcomes

1

Description
Patient’s general health survey
Timepoint
Before and after 24 weeks intervention
Method of measurement
Persian version of the SF-36 questionnaire

2

Description
Level of independence in daily activities
Timepoint
Before and after 24 weeks intervention
Method of measurement
Persian version of the Barthel index

Intervention groups

1

Description
First group: Patients who are undergo advanced weight bearing exercises (quadruped, trunk twisting and raising, tall-kneeling).
Category
Treatment - Other

2

Description
Third group: Control group, No intervention
Category
Other

3

Description
Second group: Patients who will do trunk twisting and raising exercise alone and do quadruped and tall-kneeling with quadriceps and soleus functional electrical stimulation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Physical therapy of Mostafa Rahimi
Full name of responsible person
Mostafa Rahimi
Street address
No.34, south Taheri alley, west 196 St, Tehranpars
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Tarbiat modares university
Full name of responsible person
Dr Yaghoob Fatolahi
Street address
Jalal Al Ahmad St
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Tarbiat modares university
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tarbiat Modares university
Full name of responsible person
Mostafa Rahimi
Position
Student
Other areas of specialty/work
Street address
No.34, south Taheri alley, west 196 St, Tehranpars
City
Tehran
Postal code
1655717913
Phone
+98 21 7787 3060
Fax
Email
mostafa.rahimi@modares.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tarbiat modares university
Full name of responsible person
Dr Giti Torkaman
Position
Ph.D of Physical therapy
Other areas of specialty/work
Street address
Jalal Al Ahmad St
City
Tehran
Postal code
14115-111
Phone
+98 21 82880
Fax
Email
torkamg@modares.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tarbiat modares university
Full name of responsible person
Mostafa Rahimi
Position
Student
Other areas of specialty/work
Street address
No.34, south Taheri alley, west 196 St, Tehranpars
City
Tehran
Postal code
1655717913
Phone
+98 21 7787 3060
Fax
+98 21 8288 4555
Email
mostafa.rahimi@modares.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty